

ATTORNEY'S DOCKET NUMBER

000500-328

U.S. PATENT AND TRADEMARK OFFICE

10/009601

INTERNATIONAL APPLICATION NO.
PCT/SE00/01206INTERNATIONAL FILING DATE
09 June 2000PRIORITY DATE CLAIMED
11 June 1999TITLE OF INVENTION
ABSORBENT ARTICLE THAT CONTAINS AN ACTIVE ADDITIVE AND USE OF A VISUAL INDICATOR IN AN
ABSORBENT ARTICLEAPPLICANT(S) FOR DO/EO/US
Charlotte PERSSON

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. is attached hereto (required only if not communicated by the International Bureau).
 - b. has been communicated by the International Bureau.
 - c. is not required, as the application was filed in the United States Receiving Office (RO/US).
6. An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. is attached hereto.
 - b. has been previously submitted under 35 U.S.C. 154(d)(4).
7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. are attached hereto (required only if not communicated by the International Bureau).
 - b. have been communicated by the International Bureau.
 - c. have not been made; however, the time limit for making such amendments has NOT expired.
 - d. have not been made and will not be made.
8. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).(unexecuted)
10. An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. A **FIRST** preliminary amendment.
14. A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. A substitute specification.
16. A change of power of attorney and/or address letter.
17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. Other items or information: International Preliminary Examination Report and International Search Report



21839

U.S. APPLICATION NO. (If known) 1009601		INTERNATIONAL APPLICATION NO. PCT/SE00/01206	ATTORNEY'S DOCKET NUMBER 000500-328
21. <input checked="" type="checkbox"/> The following fees are submitted:		CALCULATIONS	
Basic National Fee (37 CFR 1.492(a)(1)-(5)): Neither International preliminary examination fee (37 CFR 1.482) nor International search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$1,040.00 (960) International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$890.00 (970) International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International search fee (37 CFR 1.445(a)(2)) paid to USPTO \$740.00 (958) International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$710.00 (956) International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 (962)			
ENTER APPROPRIATE BASIC FEE AMOUNT =		\$ 1,040.00	
Surcharge of \$130.00 (154) for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)). 20 <input type="checkbox"/> 30 <input type="checkbox"/>		\$	
Claims	Number Filed	Number Extra	Rate
Total Claims	17 -20 =	0	X\$18.00 (966)
Independent Claims	2 -3 =	0	X\$84.00 (964)
Multiple dependent claim(s) (if applicable)		+\$280.00 (968)	
TOTAL OF ABOVE CALCULATIONS =		\$ 1,040.00	
Reduction for 1/2 for filing by small entity, if applicable (see below). <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		+ \$	-
		SUBTOTAL =	\$ 1,040.00
Processing fee of \$130.00 (156) for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492(f)). 20 <input type="checkbox"/> 30 <input type="checkbox"/>		+	
		TOTAL NATIONAL FEE =	\$ 1,040.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 (581) per property <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		+ \$	
		TOTAL FEES ENCLOSED =	\$ 1,040.00
		Amount to be refunded: \$	
		charged: \$	
a. <input type="checkbox"/> Small entity status is hereby claimed. b. <input checked="" type="checkbox"/> A check in the amount of \$ <u>1,040.00</u> to cover the above fees is enclosed. c. <input type="checkbox"/> Please charge my Deposit Account No. <u>02-4800</u> in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. d. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>02-4800</u> . A duplicate copy of this sheet is enclosed.			
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.			
SEND ALL CORRESPONDENCE TO: Ronald L. Grudziecki BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620			
 SIGNATURE		William C. Rowland NAME 30,888 REGISTRATION NUMBER	
		December 11, 2001 DATE	

Patent
Attorney's Docket No. 000500-328

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Charlotte PERSSON) Group Art Unit: Unassigned
Application No.: Unassigned) Examiner: Unassigned
Filed: December 11, 2001)
For: ABSORBENT ARTICLE THAT)
CONTAINS AN ACTIVE ADDITIVE)
AND USE OF A VISUAL)
INDICATOR IN AN ABSORBENT)
ARTICLE)

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-captioned patent application, please enter the following amendment.

IN THE CLAIMS:

Please cancel claim 7.

Please amend claims 1-6 as follows:

1. (Amended) An absorbent article, comprising:

at least one active additive, and

a visual indicator that indicates an activity status of the active additive.

2. (Amended) An absorbent article according to Claim 1, wherein the visual indicator changes colour in response to a change in pH or a change in the moisture content of the absorbent article as a result of the activity status of the active additive.

3. (Amended) An absorbent article according to Claim 1, wherein the visual indicator is comprised of methyl red, methyl violet, methyl orange, bromocresol lilac, Acid Blue 80, blue dye Calcocid Blud 2G, ethyl red, bromophenol blue, or bromocresol green.

4. (Amended) an absorbent article according to Claim 1, wherein the active additive is a micro-organism.

5. (Amended) An absorbent article according to Claim 1, wherein the active additive is an acid.

6. (Amended) An absorbent article according to Claim 1, wherein the visual indicator is placed on one of the uppermost layers of the absorbent product; and the visual indicator can be detected on a surface of the product.

Please add new claims 8-16 as follows:

--8. An absorbent article according to Claim 1, wherein the absorbent article is one of a diaper, a panty liner, an incontinence protector, a napkin, and a tampon.

9. An absorbent article according to Claim 1, wherein the active additive is an acid producing micro-organism.

10. An absorbent article according to Claim 1, wherein the active additive is a lactobacillus.

11. An absorbent article according to Claim 1, wherein the active additive is a lactobacillus of the strain lactobacillus plantarum LB 931 (DSM No. 41918).

12. An absorbent article according to Claim 1, wherein the active additive is citric acid.

13. An absorbent article according to Claim 1, wherein the active additive is lactic acid.

14. An absorbent article according to Claim 1, wherein the active additive is acid SAP.

15. An absorbent article according to Claim 1, wherein the visual indicator is comprised of methyl orange, methyl red, or methyl violet.

16. A method of detecting an activity status of an active additive on an absorbent article, comprising the steps of:

including in the absorbent article a visual indicator that provides a visual indication of the activity status of the active additive; and
monitoring the visual indicator for the activity status.

17. The method of claim 16, wherein the absorbent article is one of a diaper, a panty liner, an incontinence protector, a napkin, and a tampon.

REMARKS

The foregoing amendments are made to place the claims in the preferred U.S. format and to remove multiple claim dependencies.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: William C. Rowland
William C. Rowland
Registration No. 30,888

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: December 11, 2001

Attachment to Preliminary Amendment dated December 11, 2001

Marked-up Claims -

1. (Amended) An absorbent article, [such as a diaper, a panty liner, an incontinence protector, a napkin, or a tampon that includes] comprising:
at least one active additive [substance], and [characterised in that the absorbent article comprises]
a visual indicator that indicates [the] an activity status of the active additive.

2. (Amended) An absorbent article according to Claim 1, [characterised in that] wherein the visual indicator changes colour in response to a change in pH or a change in the moisture content of the absorbent article as a result of the activity status of the active additive.

3. (Amended) An absorbent article according to [any one of Claims 1 or 2]
Claim 1, wherein [characterised in that] the visual indicator is comprised of methyl red, methyl violet, methyl orange, bromocresol lilac, Acid Blue 80, blue dye Calcocid Blud 2G, ethyl red, bromophenol blue, or bromocresol green [, preferably methyl orange, methyl red or methyl violet].

4. (Amended) an absorbent article according to [any one of Claims 1-3] Claim 1, wherein [characterized in that] the active additive is a micro-organism [,preferably an

Attachment to Preliminary Amendment dated December 11, 2001

Marked-up Claims -

acid producing micro-organism, more preferably a lactobacillus, and still more preferably a lactobacillus of the strain Lactobacillus plantarum LB931 (DSM No. 41918)].

5. (Amended) An absorbent article according to [any one of Claims 1-3] Claim 1, [characterised in that] wherein the active [substance] additive is an acid [, preferably citric acid, lactic acid or acid SAP].

6. (Amended) An absorbent article according to [any one of Claims 1-5] Claim 1, [characterised in that] wherein the visual indicator is placed on one of the uppermost layers of the absorbent product; and [in that] the visual indicator can be detected on [the] a surface of the product.

10/009601
PCT/SE00/01206

WO 00/76558

ABSORBENT ARTICLE THAT CONTAINS AN ACTIVE ADDITIVE AND USE OF A VISUAL INDICATOR IN AN ABSORBENT ARTICLE

FIELD OF INVENTION

5 The present invention relates to an absorbent article that contains one or more active substances, and is characterised in that the absorbent article comprises a visual indicator that shows the activity status of the active substance.

BACKGROUND ART

10 In recent times, different additives have been included in absorbent articles. These additives, or active substances, are often included to improve the properties of the product in some way. Examples of active additives are odour-inhibiting additives, or deodorants, such as zeolites and silica for instance, as described for example in WO 97/46188, WO 97/46190, WO 97/46192, WO 97/46193, WO 97/46195 and WO 97/46196. These additives shall function mainly in the actual product. Other examples of active additives include softeners, such as lotions, in diapers, which softeners are intended to be transferred from the product to the wearer's skin. Further examples include the addition of acid superabsorbent polymers (SAP) (SE-9804390-4, SE-9804360-7), citric acid (US-A-4,583,980, GB-A-1317156), lactic acid (EP-A-0257007), or some form of acid-producing bacteria for preventing the occurrence of malodours in the products. An example of the addition of acid-producing bacteria is the addition of lactobacilli for inhibiting the growth of bacteria in the product. The lactobacilli may also be transferred to the wearer of the article, thereby enhancing defence against undesired bacteria. The addition of lactobacilli and the effect of such addition is mentioned in, *inter alia*, SE 9703669-3, SE 9502588-8, WO 92/13577, SE 9801951-6, SE 9804390-4 and SE 9902207-1.

PROBLEMS AND DEFICIENCIES WITH KNOWN TECHNOLOGY

One problem with absorbent products that contain active additives is that the substances often have limited durability. For instance, lactobacilli can be affected negatively by moisture absorption in storage, thereby impairing the effect of the lactobacilli. It is therefore important to package the products in a manner, which 5 will ensure the longest possible durability. It is also important, of course, to ensure that manufacturing conditions, storage conditions and transportation conditions are such as to make certain that the product will remain durable for as long as possible. It is often very difficult to ensure that a product has been handled optimally throughout the entire chain from its manufacture to its use. Furthermore, it can be difficult to determine whether or not the active substance in the absorbent product is 10 still fully active.

There is at present no way of determining whether or not an absorbent article that contains active additives has normal activity and function potential.

15 SUMMARY OF THE INVENTION

The invention relates to an absorbent article that contains at least one active additive, characterised in that said article comprises a visual indicator that indicates 20 the activity status of the active additive.

DEFINITIONS

By absorbent article is meant, for instance, a sanitary napkin, a diaper, an 25 incontinence protector, a tampon, a panty liner and similar products that are comprised partially of an absorbent material, for instance a cellulose material such as airlaid, LDA, chemical pulp or CTMP.

By active additive is meant a substance, an agent, or a composition that is added to 30 the absorbent article in manufacture and that is intended to change or improve the function of the article in some way. Examples of active additives include odour

inhibitors, such as zeolite and silica, softeners such as lotions, lactobacilli for inhibiting the growth of other micro-organisms, and acids, such as lactic acid and citric acid, acid SAP, and partially neutralised SAP, which are intended to lower the pH and thereby inhibit bacterial growth.

5

By visual indicator is meant a substance, a composition, or a material that gives a visual indication of changed conditions in its environment, for instance changes in pH, moisture content or temperature. Examples of visual indicators are chemical substances such as methyl red, methyl violet, methyl orange, bromocresol mauve, Acid Blue 80, blue dye Calcocid Blue 2G, ethyl red, bromophenol blue, bromocresol green, crystal violet, cresol red, thymol blue, erythrosine B, 2,4-dinitrophenol, Eriochrome™ Black T, alizarin, bromothymol blue, phenol red, m-nitrophenol, o-cresolphthaelin, -phenolphthalein, tymolphthalein, alizarin Yellow Reller, and such material as litmus paper.

15

By the activity of an active additive is meant its ability to perform its intended function. If an active additive has impaired activity, this means that its ability to produce lactic acid for instance, as in the case with lactobacilli, is worse than normal. Accordingly, by the activity status of an additive is meant the state of the activity possessed by an active additive on a given occasion.

20

DETAILED DESCRIPTION OF THE INVENTION

25

The object of the invention is to provide an absorbent article that can indicate the activity status of an active additive included in said article.

30

This object can be achieved by including in the absorbent article a visual indicator that will show a change in pH in the absorbent article, said change in pH occurring as a result of a change in the active additive. This change may be because the environment in the absorbent article has become more basic, or more acid, depending on the properties of the active additive and/or of the absorbent article.

The visual indicator will therefore preferably be selected on the basis of the properties of the active additive and the absorbent article.

According to one embodiment of the invention, this is achieved by including in the absorbent article a visual indicator that will give an indication that an included active additive is active and that it remains active during use. In this regard, the active additive produces acid, which results in a change in colour of the visual indicator. This colour change then indicates that the active additive is still active. In a preferred embodiment, the colour change takes place in the pH range of 4-7, or preferably in the pH range of 5-7.

The active additive may, for instance, be a micro-organism. According to one preferred embodiment, the active additive is an acid producing micro-organism. According to a more preferred embodiment, the active substance consists of lactobacilli. In an even more preferred embodiment, the active additive consists of lactobacilli of the strain Lactobacillus plantarum LB 931 (deposition No. (DSM): 41918).

An active additive that consists of lactobacilli is sensitive to moisture take-up. The lactobacilli are activated and consumed when stored over a long period of time in a moist environment. This means that a colour change in accordance with the aforescribed embodiment may indicate that the lactobacilli have been activated prematurely, i.e. prior to use of the product. In such a case, this will be shown by the visual indicator by virtue of a visible colour change. When no colour change can be seen on the visual indicator prior to use, this can be interpreted as meaning that the lactobacilli have still not been activated and that the product is in a fully satisfactory state. Thus, the visual indicator will normally show a colour change when use of the product is commenced.

According to one embodiment, the visual indicator shows a colour change when the active substance exhibits activity.

According to another embodiment, the visual indicator shows a colour change when the active substance has been consumed, either in the package prior to use, for instance as a result of poor storage conditions, or during use of the absorbent article.

5

According to still another embodiment, the visual indicator shows a colour change when the absorbent article has taken up moisture, for instance when the absorbent article has taken-up and contains >10 percent by weight liquid.

10

According to yet another embodiment, the active additive or substance is citric acid. Citric acid is activated when wetting the absorbent article, which is indicated by a suitable pH indicator.

15

Lactic acid, acid SAP and partially neutralised SAP may also be used as the active additive.

20

The visual indicator will preferably be applied in the lowest possible concentration, preferably in a volume of at most 0.1 ml, and more preferably in a volume of at most 0,01 ml. However, the preferred volume depends on the type of visual indicator and the type of absorbent product. Typically, the amount of the visual indicator that is used is approximately 0.1 g/cm². The total surface that will be used for application of the visual indicator is typically 1 cm². The visual indicator may be applied in a pattern, such as in stripes, flowers, dots, loops or text that appear when the visual indicator changes colour. The visual indicator may be applied on top of

25

LDA, or preferably in the nonwoven outer sheet (NW) of the absorbent article. It is preferred that the visual indicator is placed on one of the uppermost layers in the absorbent article and that the visual indicator can be detected on the surface of said article. The packaging unit in which the inventive absorbent article is packaged may be transparent, so that the visual indicator can be seen from outside the package.

30

In one embodiment, the absorbent article is, for instance, a panty liner that consists of three layers of material, to-wit an upper nonwoven layer (NW), an intermediate LDA layer and a bottom plastic layer. This article also includes an active substance, for instance lactobacilli or lactic acid, which is applied in the absorbent article. In 5 this case, the indicator may be applied on the LDA layer or on the NW layer and will conveniently be visible from outside the package.

It is important that the visual indicator is non-toxic or in not in any way harmful to the person wearing the absorbent article.

10

According to the invention, the visual indicator may be printed on the absorbent article with the aid of a print roller, or optionally on packaging film that is in contact with the article. This can be effected by rolling roll material over a print roller that is in contact with a bath of indicator liquid. The technique is well known from the printing trade.

15

The invention can be applied with absorbent articles such as diapers, panty liners, incontinence protectors, napkins and tampons, and finds the most beneficial use in panty liners, incontinence protectors and diapers.

20

ADVANTAGES AFFORDED BY THE INVENTION

25

One advantage afforded by the invention is that the consumer obtains information relating to the durability of the product and that the quality of the purchased product is fully satisfactory.

30

Another advantage afforded by the invention is that it is possible to see when the active substance has been impaired as a result of external conditions, and if so where in the handling chain from the manufacture to the use of the product the impairment has occurred. This enables the various stages in the handling chain to be

improved and also enables products whose active substance is no longer fully active to be removed from said chain.

Another important advantage afforded with the aid of the invention is that it can be
5 seen when an active substance has been active during use. This activity can be observed after use by virtue of a colour change.

2000-06-06 10:59:00.000000000

CLAIMS

1 An absorbent article, such as a diaper, a panty liner, an incontinence protector, a napkin, or a tampon that includes at least one active additive substance,
5 **characterised in that the absorbent article comprises a visual indicator that**
 indicates the activity status of the active additive.

2. An absorbent article according to Claim 1, **characterised in that the**
 visual indicator changes colour in response to a change in pH or a change in the
10 moisture content of the absorbent article.

3. An absorbent article according to any one of Claims 1 or 2,
 characterised in that the visual indicator is comprised of methyl red, methyl violet,
 methyl orange, bromocresol lilac, Acid Blue 80, blue dye Calcocid Blue 2G, ethyl
15 red, bromophenol blue, bromocresol green, preferably methyl orange, methyl red or
 methyl violet.

4. An absorbent article according to any one of Claims 1-3, **characterised**
 in that the active additive is a micro-organism, preferably an acid producing micro-
20 organism, more preferably a lactobacillus, and still more preferably a lactobacillus
 of the strain Lactobacillus plantarum LB931 (DSM No. 41918).

5. An absorbent article according to any one of Claims 1-3, **characterised**
 in that the active substance is an acid, preferably citric acid, lactic acid or acid SAP.

25 6. An absorbent article according to any one of Claims 1-5, **characterised**
 in that the visual indicator is placed on one of the uppermost layers of the absorbent
 product; and in that the visual indicator can be detected on the surface of the
 product.

7. The use of a visual indicator in an absorbent article, such as a diaper, a panty liner, an incontinence protector, a napkin or a tampon, that includes at least one active additive substance which provides an indication of the activity status of said active additive substance.